Van Hoven Decl. Ex. 5

From: Bryce Partridge [Bryce.Partridge@intusurg.com]
Sent: 9/3/2019 12:38:58 PM
To: Erin Grinberg [Erin.Grinberg@intusurg.com]; David Kelso [David.Kelso@intusurg.com]; Nicholas Yasbek [Nicholas.Yasbek@intusurg.com]; Dani Crossman [Dani.Crossman@intusurg.com]
CC: AJ Inacay [aj.inacay@intusurg.com]
Subject: FW: [EXTERNAL] da Vinci / Legacy Health - reprogrammed instrumentation concern

fyi

Bryce Partridge
Area Sales Director – West

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From: Avery, Jonathan E :LGS President LGSMC [mailto:JAvery@LHS.ORG]
Sent: Tuesday, September 03, 2019 10:36 AM
To: Bryce Partridge; Haywood, Tom L :LSO VP Interim
Subject: RE: [EXTERNAL] da Vinci / Legacy Health - reprogrammed instrumentation concern

Hi Bryce.

Thanks for calling this to our attention. We have investigated and found that, indeed, we are using some reprocessed parts at the recommendation of our CS leaders as part of our overall work to reduce costs. We have asked them to cease and desist.

-Jonathan

From: Bryce Partridge <Bryce.Partridge@intusurg.com>
Sent: Tuesday, September 3, 2019 9:30 AM
To: Avery, Jonathan E :LGS President LGSMC <JAvery@LHS.ORG>; Haywood, Tom L :LSO VP Interim <THAYWOOD@LHS.ORG>
Subject: [EXTERNAL] da Vinci / Legacy Health - reprogrammed instrumentation concern
Importance: High

External Sender – Be Suspicious of Attachments, Links, and Requests for Payment or Login Information.

Jonathan and Tom,

Hope you both are well. It has come to my attention from our data logs at corporate HQ, that Legacy Good Samaritan Medical Center is likely in breach of contract with Intuitive Surgical due to the utilization of third party reprogrammed instrumentation. There are significant safety risks associated with reprogramming and extending the lives of these instruments. Regulatory clearances for all da Vinci Instruments specify the allowable number of uses for which the instrument has been validated. Use of the product beyond the validated number of uses would require a new validation and regulatory review and clearance. Intuitive product FDA regulatory requirements for da Vinci instruments only cover instruments that have been manufactured by the legal manufacturer for the validated number of uses. The regulatory clearance does not cover instruments reprogrammed to extend the number of uses.

I'd like to schedule a call with you to discuss an action plan to ensure we educate you as best we can to ensure contract compliance and more importantly the patient safety concerns associated with reprocessing these instruments. Please advise on your availability.

Thank you, I look forward to hearing from you

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